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510(K) SUMMARY OF SAFETY AND EFFECTIVENESS:
TwinFix® Interfragmentary Compression Screw System

General Information

Proprietary Name:	**TwinFix® Interfragmentary Compression Screw System**
Common Name:	Small Bone Screw System Single/Multiple Component Metallic Bone Fixation Application and Accessories 888.3030 Target Bow Instrumentation Orthopedic manual surgical instrument 21 CFR 888.4540 Class I exempt
Proposed Regulatory Class:	Class II
Device Classification:	87 HRS 87 LXH
Submitter:	Stryker Leibinger 4100 East Milham Avenue Kalamazoo, MI 49001 800-253-7370
Submitter's Registration #:	1811755
Manufacturer's Registration #:	8010177
Contact Person:	Robin L. Rowe Regulatory Affairs Representative Telephone: 877-534-2464 x3295 Fax: 616-324-5458
Summary Preparation Date:	November 01, 2001

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Intended Use

The subject device, TwinFix® Interfragmentary Compression Screw System is indicated for fractures or arthrodesis of carpals and metacarpals, radial head and radial styloid fractures, metatarsal fractures and osteotomies of the forefoot and intra-articular arthrodesis in the wrist.

See Appendix C for equivalency.

Device Description

The Stryker Leibinger, TwinFix® Interfragmentary Compression Screw System is indicated for the treatment of fractures, psueudo-arthrosis, degenerative alterations and corrective osteotomies aiming to a functionally stable osteosysntheis such as, but not limited to: scaphoid fractures, fractures of other carpal bones, scaphoid pseudo-arthrosis, intercarpal arthrodesis, arthrodesis of finger end and metacarpal joints and fractures of ulna head and radius head.
The TwinFix® is a double cancellous bone thread screw system that is designed for in situ dynamic adjustable interfragmentary compression purposes. It has a self-tapping screw tip design with varying lengths. It may be placed using an open approach with the use of a target bow device for placement of screws or through percutaneous screw placement using K-wire as a guide to minimize the incision.

Substantial Equivalence

The TwinFix® Interfragmentary Compression Screw is identical to K961498, Resch Arthroscopic and Percutaneous Screw Fixation System in all respects of fixation applications of small bones. *A table of equivalency is provided in Appendix C.*

Robin L Rowe
Regulatory Affairs Representative
December 20, 2001

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 8 2002

Stryker Leibinger
Robin L. Rowe
Regulatory Affairs Representative
4100 East Milham Avenue
Kalamazoo, Michigan 49001

Re: K013775
Trade Name: Twinfix Interfragmentary Compression Screw System
Regulation Number: 888.3030
Regulation Name: Compression Screw with accessories
Regulatory Class: II
Product Code: HRS
Dated: December 7, 2001
Received: December 11, 2001

Dear Ms. Rowe:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K013775

510(k) Number (if known): _____

Device Name: TwinFix® Interfragmentary Compression Screw System

Indication For Use:

The Stryker Leibinger, TwinFix® Interfragmentary Compression Screw System is intended to be used for fractures or arthrodesis of carpals and metacarpals, radial head and radial styloid fractures, metatarsal fractures and osteotomies of the forefoot and intra-articular arthrodesis in the wrist.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of device Evaluation (ODE)

Prescription Use X or Over-The-Counter Use _____
(per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K013775